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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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US 7,267,100

03/10/99

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LUD5330,100-1

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HM12/0202

EXAMINER

OHMURA, N

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

02/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/265,606

Applicant(s)

ZIMMERMANN ET AL.

Examiner

Nancy Ogihara

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5 and 16-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 17) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be direction to Group Art Unit **1631**.

Applicants' preliminary amendment was received in Paper No. 3 in which Claims 1-4 and 6-15 were canceled. Consequently claims 5 and 16-19 are pending in the instant application.

Oath/Declaration

This application presents amendments (Paper No. 3) for subject matter not originally embraced in the statement of the invention. The added material which is not supported by the original disclosure is as follows: the changes in the number of base pairs in the insert and the open reading frame, (page 11, lines 23-24) alter the sequence and are therefore not supported by the specifications or the claims as originally filed; the term "FAP enzyme activity" is not supported by the specifications or the claims as originally filed. The specifications and claims are directed specifically toward FAP α proteins. Because there are numerous FAP proteins known in the art, the term "FAP enzyme activity" includes proteins additional to FAP α and therefore introduces new matter into the specification.

A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Specification

The disclosure is objected to because of the following informalities:
This application filed under former 37 CFR 1.60 lacks the necessary reference to prior applications. Following the title of the invention or as the first sentence of the specification, the

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status of the claims of priority needs to be updated to include priority to all divisional applications. Also, the current status of all nonprovisional parent applications referenced should be included. Appropriate correction is required

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5 and 16-19 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The specifications have not shown that upon removing the FAP α catalytic domain from the full length FAP α protein, the FAP α catalytic domain is functional or has activity as an independent entity separate from the original full length folded protein. Thus, the claimed invention (i.e. fusion proteins) consisting of the FAP α catalytic domain and non-FAP α proteins also have not been shown to be functional or to have activity, and therefore, lacks utility because there is no asserted utility other than for further research.

Claims 5 and 16-19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

Claims 5 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The term "FAP α catalytic domain" is not defined in the specification so that one

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skilled in the art would know what sequences, constituting the FAP α catalytic domain, would be incorporated into the proteins of claims 5 and 16-19. Although the skilled artisan would know how to make the claimed proteins, using standard available chemical or molecular biology techniques, the artisan would not know the precise sequence limits (i.e. the first and last nucleotides or residues) of the FAP α catalytic domain to, for example, clone and express the recited fusion protein.

Applicant provides evidence that FAP α possesses catalytic activity. However applicant does not provide an enabling disclosure as to how to use such catalytic activity for other than further experimentation to determine how such catalytic activity is related to the overall activity of FAP α . Nor is there any guidance as to how to use the claimed fusion proteins containing the catalytic domain of FAP α .

Claims 5 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite in the recitation of the term "FAP α catalytic domain." The term is not defined in the specification so that one skilled in the art could determine what the sequence limitations of the FAP α catalytic domain are. The specifications recite "putative catalytic domains of FAP α " (Table 2, page 13 of the specifications) and "highly conserved catalytic domains characteristic of serine proteases" (lines 22-23, page 12 of the specifications), but do not specifically define the first and last residues constituting the FAP α catalytic domain. Therefore it is not clear what the amino acid sequence limitation is for the human FAP α catalytic domain (i.e. is the catalytic domain limited to the sequences listed in SEQ ID NO's 4, 6, and 7, where the sequences are simply concatenated as listed in Table 2 with no other amino acids inserted?).

Claims 5 and 17 are vague and indefinite in the recitation of the term "portion." The term is vague and indefinite since it encompasses potentially any number of amino acids including a

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single amino acid which can be considered a portion of a protein. The specification provides no guidance as to what constitutes a portion (i.e. which sequences or how many amino acids). Therefore, the metes and bounds of the claim are unclear.

Claims 16 and 17 recite the limitation "non FAP protein". There is insufficient antecedent basis for this limitation in the claim. Examiner suggests "non FAP α protein."

Claim 17 is confusing in that it is unclear what is intended by the recitation of the phrase "wherein said at least one portion."

Claim 19 recites the limitation "fuse in protein". There is insufficient antecedent basis for this limitation in the claim. Examiner suggests "fusion protein."

Claims 5 and 16-19 are free of the prior art. The closest prior art of reference, Rettig et al (Cancer Research, vol. 53, pp. 3327-3335, 1993), does not teach or fairly suggest fusion proteins consisting of an FAP α catalytic domain and a non FAP α protein.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Ogihara whose telephone number is (703) 308-9363. The examiner can be reached Monday-Friday from 8:30-6:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Woodward can be reached at (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1631 via the PTO Fax Center located in Crystal

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Park I. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Nancy Ogihara

January 27, 2000

A handwritten signature in cursive script, appearing to read "Nancy Ogihara", is located in the upper right quadrant of the page. The signature is written in dark ink and is somewhat stylized.